

REMARKS

Reconsideration of the present application is respectfully requested. The application includes claims 24-29, 32-37, 40, 41, 46, 48-60, 62 and 64-66, pending and under consideration.

As an initial matter, Applicant acknowledges and thanks the Examiner for the indication in the outstanding Office Action that claims 64-66 are in condition for allowance. The sole remaining issue in this case is a rejection under 35 U.S.C. §112, first paragraph, as discussed below.

In the outstanding Office Action, claims 24-29, 31-37, 39-41, 44 and 46-63 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. For the reasons set forth below, Applicant submits that this rejection is overcome.

The basis for this rejection stated in the outstanding Action is that: "Claims rejected herein recite or read on various concentrations of electrolytes that were not disclosed in the originally filed specification and claims." (Office Action, Page 2). Attention is drawn in the outstanding Action to the recitation in certain claims of electrolyte concentrations of "about 223 mEq/L to about 323 mEq/L" and "about 256.4 mEq/L to about 323 mEq/L." The Examiner asserts that: "Although verbatim descriptive support is not a requirement, the originally filed disclosure fails to reasonably convey 223-323 mEq/liter. ... Given the sensitive nature of a dialysate formulation, specific electrolyte concentration range is seen to be significant and must have adequate descriptive support from the originally filed disclosure." (Office Action, Page 2).

Without acquiescing in this rejection, Applicant has above presented claim amendments that are believed to overcome this rejection. For example, claims 24, 32, 40, 46 and 54 have been amended to recite an upper concentration range for the electrolytes of 324.5 rather than 323 mEq/L. Support for this concentration is clearly provided at pages 9 and 29-30 of the specification, wherein

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individual electrolyte concentration ranges are provided for exemplary compositions including sodium, magnesium calcium, potassium, chloride, acetate and bicarbonate. Addition of the upper limits of these exemplary ranges yields a total concentration of electrolytes of 324.5 mEq/L. More particularly, the 324.5 mEq/L value is obtained by adding the “high end” concentrations of sodium (150 mEq/L), magnesium (1.5 mEq/L), calcium (4 mEq/L), potassium (4 mEq/L), chloride (120 mEq/L), acetate (5 mEq/L) and bicarbonate (40 mEq/L). Thus, a person of ordinary skill in the art at the time the application was filed would readily appreciate that the present specification provides sufficient written description to establish that the inventor was in possession of this concentration value at the time the application was filed as an upper limit of a concentration range for electrolytes in a dialysate composition.

With respect to the lower end of the range recited in claims 24, 32, 40, 46 and 54, as amended, Applicant submits that this concentration is also supported by sufficient written description in the specification to establish that the inventor was in possession of this value at the time the application was filed. Support for this concentration is also clearly provided at pages 9 and 29-30 of the specification, wherein individual electrolyte concentration ranges are provided for exemplary compositions including sodium, magnesium calcium, potassium, chloride, acetate and bicarbonate. Addition of the lower limits of these exemplary ranges yields a total concentration of electrolytes of 256.4 mEq/L. More particularly, the 256.4 mEq/L value is obtained by adding the “low end” concentrations of sodium (130 mEq/L), magnesium (0.4 mEq/L), calcium (2 mEq/L), potassium (1 mEq/L), chloride (90 mEq/L), acetate (3 mEq/L) and bicarbonate (30 mEq/L).

In addition to the above, Applicant submits that the outstanding Action indicates a recognition that the 256.4 mEq/L value is proper. The Action states at page 2 that: “Various specification disclosure (e.g. pp. 9, 29-30) and original claim 20 convey a minimum of 256.4 mEq/liter and maximum of 572.5 mEq/liter.” While Applicant believes that the 572.5 value in the

above statement is in error, Applicant submits that this statement at the least represents an acknowledgement by the Examiner that the 256.4 value is appropriate as recited in the above-identified claims. With respect to the 572.5 value, it appears that the 250 µg/dl concentration of iron recited in the specification may have been erroneously included in this value.

In view of the above, Applicant submits that a person of ordinary skill in the art at the time the application was filed would have readily appreciated, in view of the information presented in the specification, that Applicant was in possession of the electrolyte concentration range "about 256.4 to about 324.5" presented in claims 24, 32, 40, 46 and 54, as amended.

As noted in the outstanding Action, multiple claims pending in the present application recite concentration ranges for dialysate concentrates that have concentrations from about 30 to about 40 times greater than an end-use dialysate. For example, in claim 53, as amended, the 7692 mEq/L value represents a concentration 30 times greater than 256.4 mEq/L. Similarly, in claim 53, as amended, the 12,980 mEq/L value represents a concentration 40 times greater than 324.5 mEq/L. These values are also recited in claims 53, 55 and 62. Applicant submits that this range finds adequate support in the written description to establish that the inventor was in possession of the claimed invention at the time the application was filed.

In view of the above explanations, Applicant submits that claims 24-29, 32-37, 40, 41, 46, 48-60 and 62, as amended, satisfy the written description requirement of 35 U.S.C. §112, first paragraph, and that the rejection asserted in the outstanding Office Action is overcome. Applicant therefore respectfully requests withdrawal of this rejection.

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In view of the above, Applicant respectfully submits that the present application, as amended and including pending claims 24-29, 32-37, 40, 41, 46, 48-60, 62 and 64-66, is in condition for allowance.

Action to that end is respectfully requested.

Attached hereto are 3 pages that present a marked-up version of the changes made to claims 24, 32, 40, 46, 53-55 and 62 by the current amendment. This attachment is captioned "VERSION WITH MARKED CHANGES".

If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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VERSION WITH MARKED CHANGES

Claims 31, 39, 44, 47, 61 and 63 have been cancelled.

Claims 24, 32, 40, 46, 53-55 and 62 have been amended as follows:

24. (Thrice Amended) An aqueous composition, comprising:

water;

a plurality of electrolytes dissolved in the water, the electrolytes having a concentration in the water of from about [223] 256.4 mEq/L to about [323] 324.5 mEq/L, and the electrolytes proportioned for dialysis of a patient; and

an iron complex dissolved in the water, the complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, the iron complex having a concentration in the water to provide an iron concentration of from about 1 to about 250 µg/dl.

32. (Four Times Amended) A method for making an aqueous composition useful as a dialysate, comprising, dissolving into water (i) a plurality of electrolytes in an amount effective to provide an electrolyte concentration in the water of from about [223] 256.4 mEq/L to about [323] 324.5 mEq/L, the electrolytes proportioned for dialysis of a patient and (ii) an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000 in an amount effective to provide an iron concentration in the water of from about 1 to about 250 µg/dl, to provide an aqueous composition.

40. (Thrice Amended) A method for making an aqueous composition useful as a dialysate, comprising:

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providing a first aqueous solution of electrolytes, the electrolytes having a concentration in the solution of from about [223] 256.4 mEq/L to about [323] 324.5 mEq/L and the electrolytes being proportioned for dialysis of a patient; and

introducing into the first solution an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, to provide a second aqueous solution useful as a dialysate, the second aqueous solution having an iron concentration of from about 1 to about 250 µg/dl.

46. (Amended) An aqueous composition, comprising:

water;

a plurality of electrolytes dissolved in the water; and

an iron complex dissolved in the water, the complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000;

wherein the electrolytes and the iron complex have concentrations in the water whereby the composition is effective for dilution to provide a dialysate having an electrolyte concentration of from about [223] 256.4 mEq/L to about [323] 324.5 mEq/L and an iron concentration of from about 1 to about 250 µg/dl.

53. (Amended) The composition in accordance with claim 46, wherein the electrolytes have a concentration in the water of from about 7692 mEq/L to about [12,940] 12,980 mEq/L.

54. (Amended) A method for making an aqueous composition useful as a dialysate concentrate, comprising, dissolving into water (i) a plurality of electrolytes and (ii) an iron complex

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comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, to provide an aqueous composition;

wherein the electrolytes and the iron complex have concentrations in the water whereby the composition is effective for dilution to provide a dialysate having an electrolyte concentration of from about [223] 256.4 mEq/L to about [323] 324.5 mEq/L and an iron concentration of from about 1 to about 250 µg/dl.

55. (Amended) The method in accordance with claim 54, wherein the electrolytes have a concentration in the water of from about [6690] 7692 mEq/L to about [12,940] 12,980 mEq/L and wherein the iron complex has a concentration in the water effective to provide an iron concentration in the water of from about 0.03 to about 10 mg/dl.

62. (Amended) A method for making an aqueous composition useful as a dialysate concentrate, comprising:

providing a first aqueous solution of electrolytes, the electrolytes having a concentration in the solution of from about [6690] 7692 mEq/L to about [12,940] 12,980 mEq/L; and

introducing into the first solution an iron complex comprising one or more divalent or trivalent iron ions and one or more anions and having a molecular weight of less than about 50,000, to provide a second aqueous solution useful as a dialysate concentrate, the second aqueous solution having an iron concentration of from about 0.03 to about 10 mg/dl.